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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,002	10/22/2003	Laurie B. Gower	UF-304XC2	5666

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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05/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/691,002	Applicant(s) GOWER ET AL.	
	Examiner David M. Naff	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2006 and 26 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6, 8, 9, 11-16, 18-24, 27-29, 31-58, 62-74 and 77-79 is/are pending in the application.
- 4a) Of the above claim(s) 40-58 and 62-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 8, 9, 11-16, 18-24, 27-29, 31-39 and 77-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

An amendment of 12/27/06 amended claims 1-3, 5, 6, 8, 9, 11, 13, 18, 19, 22-24, 29, 31-40, 42, 44, 45, 62, 64, 66, 69, 71, 72 and 74, added new claims 77-79, and canceled claims 4, 7, 10, 17, 25, 26, 30, 59-61, 75 and 76, a supplemental amendment of 12/27/06 amended claims 3, and a supplemental amendment of 1/26/07 amended claim 40, 41, 43, 51 and 54-57.

A Declaration by Laurie B. Gower under 37 CFR 1.132 was filed with the amendment of 12/27/06.

Claims in the application are 1-3, 5, 6, 8, 9, 11-16, 18-24, 27-29, 31-58, 62-74 and 77-79.

Claims 40-58 and 62-74 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/20/06.

Claims examined on the merits are 1-3, 5, 6, 8, 9, 11-16, 18-24, 27-29, 31-39 and 77-79.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1-3, 5, 8, 11-13, 15, 24, 27-29, 31 and 77-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Olszta (Biomimetic Mineralization of Type-I Collagen) (R9 on 1449 of 5/12/04) or Olszta (Biomimetic Mineralization of Type-I Collagen) (R11 on 1449 of

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5/12/04) or Olszta (Biomimetic Mineralization of Collagen for Nanostructured Composites (R27 on 1449 of 3/15/04)).

The claims are drawn to an organic/inorganic composite comprising and organic fluid-swellaable fibrous matrix comprising fibers and
5 interstitial spaces, and an inorganic mineral phase of amorphous or crystalline structure that coats and infiltrates each of the fibers, and is embedded in the interstitial spaces.

Olszta R9, R11 or R27 disclose mineralization of collagen by preparing a calcium chloride solution, addition of short chain acidic
10 polymers (poly-L-aspartic acid and polyacrylic acid), addition of a collagen substrate, and vapor diffusion of ammonium carbonate. For example, see the 5th page of R9 and R27, and pages 15 and 16 of R11.

The mineralization of collagen as disclosed by Olszta R9, R11 or R27 produces a composite that is the same as presently claimed. The
15 collagen of the R9, R11 or R27 has fibers and interstitial spaces as claimed, and the composite produced by Olszta R9, R11 or R27 inherently has an inorganic mineral phase of amorphous or crystalline structure that coats and infiltrates each of the fibers, and is embedded in the interstitial spaces. The calcium chloride solution,
20 acidic polymer and ammonium carbonate of Olszta R9, R11 or R27 form a mineral precursor of Olszta R9, R11 or R27. The features of dependent claims are inherently contained by the composite produced as disclosed by Olszta R9, R11 or R27.

Claim Rejections - 35 USC § 103

Claims 6, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olszta R9, R11 or R27 in view of Silver et al (5,532,217).

5 Claims 6 and 16 require hydroxyapatite as the mineral, and claim 18 requires collagen fibers having a long axis and abutting fibrils, and hydroxyapatite crystals oriented in the crystallographic direction along the long axis of the fibers.

 Silver et al disclose mineralization of collagen fibers with
10 hydroxyapatite. For example, see claim 8, col 4.

 It would have been obvious to carry out the mineralization of Olszta R9, R11 or R27 with hydroxyapatite as suggested by Silver et al since hydroxyapatite contains calcium phosphate which Olszta R9, R11 or R27 can use for mineralization. Crystals of hydroxyapatite will
15 inherently be formed and oriented as claimed.

Claim Rejections - 35 USC § 103

Claims 9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olszta R9, R11 or R27 in view of Rhee et al (5,800,541).

20 The claims require the matrix to be surface-modified.

 Rhee et al disclose modifying collagen to bind biological agents to a collagen-synthetic polymer matrix for use as an implant (paragraph bridging cols 17 and 18, and col 18, lines 20-50).

It would have been obvious to modify the collagen of the composite of Olszta R9, R11 or R27 as suggested by Rhee et al to bind biological agents.

Claim Rejections - 35 USC § 103

5 Claims 19-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olszta R9, R11 or R27 in view of Liu (6,300,315 B1).

The claims require the composite to contain a biologically active agent.

10 Liu discloses producing a mineralized collagen membrane by adding calcium and phosphate ions to a collagen slurry (col 2, line 53 to col 3, line 21) to form precipitated calcium phosphate. A drug may be incorporated in the membrane (col 3, lines 57-65). Drugs include antibiotics, bone morphogenetic proteins, bone growth factors, skin growth factors, antiscarring agents and/or mixtures.

15 It would have been obvious to incorporate a biologically active agent when preparing the composite of Olszta R9, R11 or R27 to obtain the function of the agent as suggested by Liu incorporating a drug that is a biologically active agent in a mineralized collagen membrane.

20 ***Claim Rejections - 35 USC § 103***

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 19-21 and 23 above, and further in view of Rhee et al.

25 The claim requires the biologically agent to be pendantly attached to the matrix.

Rhee et al is described above.

When incorporating a biologically active agent as suggested by Liu as above, it would have been obvious to attach the biologically active agent pendantly to a reactive group formed on the collagen of Olszta R9, R11 or R27 as suggested by Rhee et al rather than incorporating the agent in the collagen.

Claim Rejections - 35 USC § 103

Claims 32, 33, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olszta R9, R11 or R27 in view of Connelly et al (6,995,013 B2).

Claims 32 and 33 require the comprise to comprise seeded cells. Claims 35 and 36 require the composite to be in the form of a lamellae and the lamellae to be arranged concentrically around a central void, respectively.

Connelly et al disclose using collagen to form a cell-scaffold having five layers (col 13, lines 38-42) for producing tissue, and that bone structure contains osteons formed of lamellae (col 2, lines 24-37).

It would have been obvious to seed the collagen of Olszta R9, R11 or R27 with cells as suggested by Connelly et al to form tissue. It would have been further obvious to form the collagen of Olszta R9, R11 or R27 as a lamellae arranged concentrically around a central void as suggested by Connelly et al.

Claim Rejections - 35 USC § 103

Claims 34 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olszta R9, R11 or R27 in view of Song et al (5,418,222).

5 Claim 34 requires the matrix to be a film. Claims 37-39 require a plurality of matrices having an adhesive layer between each matrix.

Song et al disclose a multiple layer collagen film having an adhesive between each layer for delivery of pharmaceuticals (col 5, lines 58-61).

10 It would have been obvious to provide the collagen of Olszta R9, R11 or R27 as a multiple layer film and adhere the layers together with an adhesive as suggested by Song et al when desiring the function of a multiple layer film. The layers of Song et al are parallel as required by claim 38, and providing an alternating orientation as in
15 claim 39 would have been obvious for putting a different pharmaceutical in each layer.

Response to Arguments

An additional 37 CFR § 1.132 Declaration by co-inventor, Dr. Laurie B Grower, filed 12/27/06 states that Drs. Douglas, Olszta and
20 Grower contributed to the conception of mineralizing a collagen matrix using the process of the invention. The declaration also states that the experiments described in Olszta R9, R11 and R27, were carried out by Drs. Olszta and Grower to confirm that the process conceived by Drs. Douglas, Olszta and Grower worked for its intended purpose.
25 However, the concept of the claimed invention is much broader than the

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specific process described in Olszta R9, R11 and R27, and the declaration fails to establish that Dr. Douglas was also involved in conceiving the specific procedures described by in Olszta R9, R11 and R27. The declaration states the Dr. Douglas was not directly involved in the experiments described in Olszta R9, R11 and R27. Conceiving a generic invention as claimed does not establish conceiving a specific species as described by in Olszta R9, R11 and R27 within the scope of the generic invention. The embodiment of the invention involving Dr. Munisamy as stated in the declaration is not claimed, and the embodiment involving Dr. Wheeler (claims 20, 32 and 33) as indicated in the declaration is rejected under 35 USC 103 and are not described by Olszta R9, R11 and R27. Therefore, Olszta R9, R11 and R27 are proper references with respect to claims drawn to the embodiments Drs. Munisamy and Wheeler contributed as inventors.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

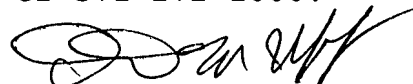
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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



David M. Naff
Primary Examiner
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